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#1634  
11/5/02

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re the Application of:

Group Art Unit: 1634

SEP 20 2002

GUIDA et al.

Examiner:

TECH CENTER 1600/2900

Serial No.: 10/085,612

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

Filed: February 26, 2002

Atty. File No.: 4389-5-C1

For: "METHODS FOR EVALUATING THE  
ABILITY TO METABOLIZE  
PHARMACEUTICALS AND  
COMPOSITIONS THEREFOR"

## CERTIFICATE OF MAILING

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SHERIDAN ROSS P.C.

BY: Christine Jaquet

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OCT 22 2002

Assistant Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

Dear Sir:

Pursuant to Applicant's duty of disclosure under 37 CFR § 1.56 and 37 CFR §§ 1.97-1.98, Applicant hereby provides a copy of each of the documents identified on the enclosed PTO Form 1449, although Applicant does not admit that any of such documents, alone or in any combination, are considered to be material to patentability as defined in 37 CFR § 1.56(b). Moreover, the inclusion of these documents is not to be construed as an admission by Applicant that each such document is prior art as to the above-identified patent application.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Robert D. TraverRobert D. Traver  
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SHEET 1 OF 1

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| FORM PTO-1449<br>U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE<br><br>INFORMATION DISCLOSURE STATEMENT<br>(Use several sheets if necessary) | ATTY. DOCKET NO.<br>4389-5-C1    | SERIAL NO.<br>10/085,612 |
|  | APPLICANT<br>GUIDA et al.        |                          |
|  | FILING DATE<br>February 26, 2002 | GROUP ART<br>1634        |

## FOREIGN PATENT DOCUMENTS

|  |     | DOCUMENT<br>NUMBER | DATE    | COUNTRY | CLASS | SUB<br>CLASS | TRANSLATION |    |
|--|-----|--------------------|---------|---------|-------|--------------|-------------|----|
|  |     |                    |         |         |       |              | YES         | NO |
|  | A1. | WO 99/13106        | 3/18/99 | PCT     |       |              |             |    |
|  |     |                    |         |         |       |              |             |    |

## OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

|     |  |
|-----|--|
| A2. | Felix et al., "Association of CYP3A4 genotype with treatment-related leukemia"; <u>Proc. Natl. Acad. Sci. USA</u> ; Vol. 95; 1998, pps. 13176-81.  |
| A3. | Howells et al., "Association of Glutathione S-Transferase GSTM1 and GSTT1 Null Genotypes with Clinical Outcome in Epithelial Ovarian Cancer"; <u>Clinical Cancer Research</u> ; Vol. 4; 1998, pps. 2439-45.  |
| A4. | Jungnelius, et al., "Similar Toxic Effect of 1,3-BIS(2-Chloroethyl)-1-Nitrosourea on Lymphocytes from Human Subjects Differing in the Expression of Glutathione Transferase M1-1"; <u>Biochemical Pharmacology</u> ; Vol. 47:10; 1994, pps. 1777-80        |
| AE  | Kirches et al., "MGMT- and P450 3A-inhibitors do not sensitize glioblastoma cell cultures against nitrosoureas"; <u>Clinical Neuropathology</u> ; Vol. 18:1; 1999, pps. 1-8  |
| AF  | Lizard-Nacol et al., "Glutathione S-transferase M1 null genotype: lack of association with tumour characteristics and survival in advanced breast cancer"; <u>Breast Cancer Res.</u> ; Vol. 1:1; 1999, pps. 81-87.   |
| AG  | Nakamura et al., "Apparent Low Frequency of Sequence Variability within the Proximal Promoter Region of the Cytochrome P450 (CYP) 3A5 Gene in Established Cell Lines from Japanese Individuals"; <u>Biol. Pharm. Bull.</u> ; Vol. 24:8; 2001, pps. 954-57. |
|     |  |

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|---|-----------------|
| EXAMINER  | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |